

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SANDOZ INC. AND RAREGEN,
LLC,

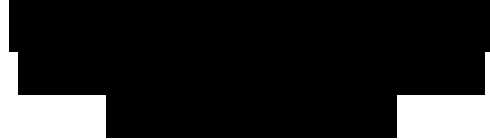
Plaintiffs,

V.

UNITED THERAPEUTICS
CORPORATION AND SMITHS
MEDICAL ASD, INC.,

Defendants.

Civil Action No. 3:19-cv-10170-BRM-
LHG



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Oral argument requested

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**DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION TO DISMISS
UNDER FED. R. CIV. P. 12(b)(6)**

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Plaintiffs provide no justification for the most glaring flaw in the Complaint: their failure to plead that they were foreclosed from a market, as opposed to one means (among many) of entering it. In fact, Plaintiffs allege in the Complaint that pumps other than the CADD-MS[®] 3 can be and have been developed to administer subcutaneous treprostinil. Compl. ¶¶ 42–44. All of this is apparent on the Complaint’s face and is fatal to Plaintiffs’ claims. For this and the reasons discussed below and in Defendants’ opening brief, this case should be dismissed.

ARGUMENT

I. Plaintiffs Fail To Allege Foreclosure.

To pursue an antitrust claim—however styled—Plaintiffs must plead they could not have accessed the market by purchasing or developing a delivery system other than the one United Therapeutics Corporation (“UTC”) happened to have used for Remodulin[®]. They fail to do so.

To be sure, Plaintiffs assert—absent any supporting allegations—that they “are unable to sell their [generic treprostinil] for use in subcutaneous treatments.” *Id.* ¶ 52. But that is a conclusion unsupported by predicate allegations. They do not—and cannot—allege there are no effective alternative means to access the purported market for subcutaneously administered treprostinil. In fact, they plead in detail that alternative means can be developed by firms that—unlike Sandoz and RareGen—employ foresight and business acumen, and make the necessary

investment. *Id.* ¶¶ 42–44 (UTC’s development efforts). The only reasonable inference from the facts pled by Plaintiffs is that, had they done the same, Plaintiffs would have had access to 100% of the claimed market. Plaintiffs’ failure to plead the lack of alternative means is fatal to each of their antitrust claims. *Int’l Constr. Prods. LLC v. Caterpillar Inc.*, 2016 WL 264909, at *5 (D. Del. Jan. 21, 2016); *see also Genus Lifesciences Inc. v. Lannett Co.*, -- F. Supp. 3d --, 2019 WL 1981186, at *14–15 (N.D. Cal. May 3, 2019) (lack of alternatives essential to Section 2 claim); *Syncsort Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 332–33 (D.N.J. 1999) (same); *Granite Partners, L.P. v. Bear, Stearns & Co.*, 17 F. Supp. 2d 275, 295–96 (S.D.N.Y. 1998) (same for Section 1 claim).¹

A. Plaintiffs’ Cases Have No Bearing on This Issue.

Plaintiffs pin their entire argument on the assertion that *United States v. Dentsply International, Inc.*, 399 F.3d 181 (3d Cir. 2005), somehow excuses their failure to plead the lack of alternative means to access the market. *Opp.* at 7–8. That misreads *Dentsply*, and badly. In *Dentsply*, the court considered the percentage of the market that must be foreclosed to support an antitrust claim, *assuming the proper predicate has been satisfied*—namely, that the distribution

¹ Plaintiffs urge the Court to ignore *Genus Lifesciences*, *Syncsort*, and *Granite Partners* because those cases do not address exclusive dealing claims, while simultaneously protesting that they pled claims *other* than exclusive dealing claims. *Opp.* at 9–10. Those cases show the need to plead lack of alternatives applies to *all* of Plaintiffs’ claims, not just exclusive dealing claims.

channel allegedly foreclosed is the only effective means to access the market. 399 F.3d at 191.² The complaint in *Dentsply* explicitly alleged the predicate lack of alternatives. Compl. ¶ 33, *Dentsply*, 1999 WL 35141402 (D. Del. 1999). The same is true of *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012). See Compl. ¶¶ 27–32, *ZF Meritor*, 2006 WL 3427206 (D. Del. 2006). Plaintiffs’ Complaint here has no similar allegations. That failure is fatal, as has been recognized by district courts in this Circuit even after both *Denstply* and *ZF Meritor*. See *Int’l Constr. Prods.*, 2016 WL 264909, at *5.

Plaintiffs’ other cases also fail to support the novel theory that they are somehow excused from pleading a lack of alternative means. Plaintiffs’ reliance on *BanxCorp v. Bankrate, Inc.*, 2009 WL 2986126 (D.N.J. Sept. 14, 2009), and *Fresenius Kabi USA, LLC v. Par Sterile Products, LLC*, 2017 WL 548944 (D.N.J. Feb. 10, 2017), is misplaced. Contrary to Plaintiffs’ assertion, neither case supports the proposition that a plaintiff need only plead a conclusory claim that “competition was foreclosed” to meet its burden. Opp. at 11. In both cases, the plaintiffs did more than simply announce they had been foreclosed from the

² The reason the predicate matters is obvious: Alleging foreclosure from a particular *means* of accessing the market tells the Court nothing of the percentage of *market* foreclosure where alternative means of entry exist. See *Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997) (“If competitors can reach the ultimate consumers of the product by employing existing or potential alternative channels of distribution, it is unclear whether such restrictions foreclose from competition *any* part of the relevant market.”).

market—they supported those allegations with the necessary factual claims. *See* 2d Am. Compl. ¶ 115, *BanxCorp*, 2008 WL 5584977 (D.N.J. 2008); Compl. ¶ 118, *Fresenius*, 2016 WL 4035479 (D.N.J. 2016).³

B. Plaintiffs Cannot Distinguish Cases Dismissing Claims for Failure To Allege the Absence of Alternative Means of Distribution.

Courts, including in the Third Circuit, consistently dismiss antitrust claims where plaintiffs fail to allege a lack of alternatives. In *International Construction Products*, the district court granted the motion to dismiss because the plaintiff “fail[ed] to adequately plead the lack of alternative channels of distribution.” 2016 WL 264909, at *5. *International Construction Products* is on all fours with this case, and Plaintiffs’ attempt to distinguish it misses the mark. There, like here, the complaint offered only the conclusory allegation that the plaintiff was “deprived of any feasible way to reach the consumers,” without any supporting allegations. *Id.* (internal quotation marks omitted). That is the precise fault that infects Plaintiffs’ Complaint here. Plaintiffs rest their foreclosure allegation on the unsupported statement that they are unable to access the market. Compl. ¶ 52. Such “conclusory or bare-bones allegations” are insufficient to “survive a motion to

³ Plaintiffs falsely claim that only two of the three avenues of distribution were occluded in *Fresenius*. *See* Opp. at 12 (“[D]efendant engaged in exclusive contracts with two of the three available distributors.”). The *Fresenius* court clearly stated that “all three” avenues of distribution were blocked. 2017 WL 548944, at *3. In any event, Plaintiffs here merely allege “foreclosure” as to a single avenue, with no mention of the others. Compl. ¶ 74.

dismiss.” *Hughes v. United Parcel Serv., Inc.*, 639 F. App’x 99, 102 (3d Cir. 2016) (brackets and internal quotation marks omitted).

The same is true of *American National Manufacturing Inc. v. Select Comfort Corp.*, 2016 WL 9450472 (C.D. Cal. Sept. 28, 2016). Plaintiffs’ attempt to distinguish that case by noting that it involved a plaintiff who was foreclosed from only one of many potential suppliers, Opp. at 10, is no distinction at all. The plaintiff there claimed the defendant had prohibited it from competing by signing an exclusive supply agreement with the manufacturer of a necessary input. 2016 WL 9450472, at *7. The plaintiff alleged it had been foreclosed from “access to a high quality producer of [the necessary input].” *Id.* The court dismissed the complaint for failure to plead foreclosure because the plaintiff did not “assert that there are no other comparably priced high quality producers . . . from whom Plaintiffs could purchase such material.” *Id.* That is exactly what Plaintiffs did here: They merely allege they were entirely foreclosed from a single means of delivering subcutaneous treprostinil. The result should be the same.

C. Plaintiffs’ Factual Disputes Are Irrelevant.

To distract from their pleading failures, Plaintiffs claim disagreements over facts that have no bearing on this Motion. Opp. at 12–15. To resolve Defendants’ Motion, the Court need look no further than the four corners of the Complaint, which fails to properly plead foreclosure. For example, whether or not Plaintiffs

knew about “Defendants’ secret agreements,” *id.* at 12, has nothing to do with Plaintiffs’ failure to allege they were foreclosed from the market, as opposed to a single means of entering it. And Plaintiffs’ claim that they did not know about the discontinuation of the CADD-MS 3 cartridges, *id.* at 15, does not relieve them of their burden to plead that Defendants actually foreclosed them from the market.

II. Plaintiffs’ New Characterizations of Their Claims Do Not Save Them.

In an effort to avoid the consequences of their failure to plead foreclosure, Plaintiffs now attempt to rewrite their Complaint to characterize their antitrust claims as unlawful tying and conspiracy to monopolize—and then fault Defendants for not addressing these unpled claims. Plaintiffs’ characterization games are ineffectual, however, because the same underlying deficiencies still apply, irrespective of what Plaintiffs call their claims.

A. Plaintiffs Do Not Plead Facts To Support a Tying Claim.

Seeking to amend their Complaint in their opposition, Plaintiffs assert they always intended to plead a tying claim—the alleged tie of the sale of Remodulin (the purported “tied” product) to the purchase of cartridges (the purported “tying” product)—though that claim appears nowhere in their Complaint. *Opp.* at 16–17. Even if Plaintiffs actually had pled a tying claim, it still would merit dismissal. It is hornbook law that “the antitrust concern over tying arrangements is limited to those situations in which the seller can exploit its power in the market for the tying

product to force buyers to purchase the tied product when they otherwise would not, thereby restraining competition in the tied product market.” *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 442–43 (3d Cir. 1997) (brackets omitted). As a result, a tying claim must be dismissed for failure to allege the absence of products reasonably interchangeable with the alleged tying product—here, the cartridges. *Id.* That is just what Plaintiffs fail to do here. Whether analyzed as a failure to plead the contours of a tying product market or a failure to plead the requisite market power in that market due to a lack of alternatives, the result is the same: Plaintiffs’ failure to allege the absence of potential or actual substitutes for the CADD-MS 3 pumps and cartridges dooms their claims. *See, e.g., Marchese v. Cablevision Sys. Corp.*, 2011 WL 149917, at *6 (D.N.J. Jan. 14, 2011) (dismissing tying claim “for failure to plead a valid relevant market”).

B. Plaintiffs Do Not Plead Sufficient Facts To Support a Conspiracy To Monopolize Claim.

Plaintiffs’ single conclusory assertion of a “conspiracy to monopolize,” *see* Compl. ¶ 84, also is insufficient. To plead a proper conspiracy to monopolize claim, a plaintiff must allege “(1) an agreement to monopolize; (2) an overt act in furtherance of the conspiracy; (3) a specific intent to monopolize; and (4) a causal connection between the conspiracy and the injury alleged.” *Howard Hess Dental Labs. Inc. v. Dentsply Int’l, Inc.*, 602 F.3d 237, 253 (3d Cir. 2010). One searches in vain to find in Plaintiffs’ Complaint any such allegations as to each Defendant.

It is well-settled that simply invoking the phrase, “conspiracy to monopolize”—which is all Plaintiffs here have done—does not come close to fulfilling a plaintiff’s obligation. *Globespanvirata, Inc. v. Tex. Instrument, Inc.*, 2006 WL 543155, at *3–6 (D.N.J. Mar. 3, 2006) (dismissing conspiracy to monopolize claim for failure to allege required element); *Desai v. Impacta, S.A.*, 1990 WL 132709, at *11–12 (D.N.J. Sept. 7, 1990) (same).

In particular, as to the “essential element” of specific intent to monopolize, the Third Circuit has held that alleging the existence of exclusive dealing agreements is not sufficient to allege specific intent. *Howard Hess Dental Labs.*, 602 F.3d at 258 (“we cannot infer the [Defendants’] specific intent from their mere participation” in agreements). Further, as Defendants stated in their Motion To Dismiss, because Plaintiffs fail to allege a lack of alternatives—*i.e.*, that Defendants possessed market power—Plaintiffs have failed to allege that Defendants’ conduct could have any anticompetitive effect, which also dooms any conspiracy to monopolize claim. *Dickson v. Microsoft*, 309 F.3d 193, 211 (4th Cir. 2002). Plaintiffs’ conclusory assertion of a conspiracy to monopolize does not cure their pleading defects.

III. Plaintiffs Fail To Allege That Defendants’ Agreement Is Anticompetitive.

Plaintiffs’ antitrust claims should also be dismissed for the independent reason that they have not and cannot allege anticompetitive conduct. To try to

circumvent this problem, Plaintiffs contend that no court has dismissed an exclusive dealing claim on the grounds that the alleged arrangement was procompetitive. *See* Opp. at 15 (citing cases). That is not true.

As the antitrust laws provide—and common sense dictates—a company does not engage in anticompetitive conduct, but rather legitimate procompetitive conduct, when it invests its resources to create assets, facilities, or distribution networks to enable it to compete more effectively and then merely prevents its rivals from free-riding on its efforts by accessing the subject matter of its investment. *See* Defs.’ Mot. at 13 (citing *Gemini Concerts, Inc. v. Triple-A Baseball Club Assocs.*, 664 F. Supp. 24, 26–27 (D. Me. 1987)); *see also* *Seagood Trading Corp. v. Jerrico, Inc.*, 924 F.2d 1555, 1572–73 (11th Cir. 1991) (company does not engage in anticompetitive conduct by investing significant resources to develop distribution chain and denying free-riding rival access to chain).⁴

Because exclusive dealing arrangements so often serve procompetitive ends, many courts hold they are presumptively legal under the antitrust laws. *See, e.g.,* *CAE Inc. v. Gulfstream Aerospace Corp.*, 203 F. Supp. 3d 447, 454–55 (D. Del. 2016); *see also* *Cinema Vill. Cinemart, Inc. v. Regal Entm’t Grp.*, 2016 WL

⁴ “A combination of competitors that makes possible production that would not otherwise occur at all clearly brings a legitimate benefit.” 7 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1504c (4th ed. 2018).

5719790, at *4 (S.D.N.Y. Sept. 26, 2016), *aff'd*, 708 F. App'x 29 (2d Cir. 2017); *Planetarium Travel, Inc. v. Altour Int'l, Inc.*, 97 F. Supp. 3d 424, 432 (S.D.N.Y.), *aff'd*, 622 F. App'x 40 (2d Cir. 2015). Contrary to Plaintiffs' claim, courts have dismissed exclusive dealing claims at the pleading stage because the conduct alleged could not be considered anticompetitive. *See, e.g., CAE*, 203 F. Supp. 3d at 455 (dismissing plaintiff's claim for failing to plead necessary "hallmarks" that overcome presumption of lawfulness); *Cinema Village*, 2016 WL 5719790, at *5; *Natco Pharma Ltd. v. Gilead Sci., Inc.*, 2015 WL 5718398, at *5 (D. Minn. Sept. 29, 2015) (antitrust claim alleging foreclosure of generic PAH drug from market dismissed for failure to allege anticompetitive conduct).

Here, rather than plead any anticompetitive conduct, Plaintiffs plead facts confirming the agreement's procompetitive effects. Plaintiffs' Complaint describes an output-*enhancing* arrangement: Faced with Smiths' discontinuation of essential inputs, UTC stepped up to fund and purchase an interim supply so it had time to develop alternatives, and that very supply is what Plaintiffs now want to access. Compl. ¶ 51. Plaintiffs chose to allege in their Complaint the specific facts that animated UTC's decision to partner with Smiths. Those factual allegations must be accepted as true for purposes of this motion. *See* Mot. at 3 n.1.

In their bid now to reel back that admission, Plaintiffs try to create the illusion that the facts are disputed by speculating that it is possible Smiths may

have continued making the cartridges, sold them to Plaintiffs, or been able to license the design to Plaintiffs.⁵ Opp. at 15. But Plaintiffs do not cite any factual allegations in support of these claims. Plaintiffs' rank speculation cannot satisfy their burden to plead facts that give rise to a plausible claim for relief. Because the Complaint clearly alleges facts showing that Defendants' conduct cannot be deemed anticompetitive and Plaintiffs point to no facts showing otherwise, Plaintiffs' antitrust claims should be dismissed for this independent reason.

IV. RareGen Lacks Antitrust Standing.

Neither RareGen's marketing responsibilities nor its right as an investor to share proceeds from Sandoz's sales of generic treprostinil create antitrust standing.

RareGen does not dispute that sales representatives lack antitrust standing, as their injuries are both too remote and wholly derivative of any suffered by the product manufacturer. Mot. at 16. As the Third Circuit holds, marketing companies lack antitrust standing because they are "not competitors of companies

⁵ Plaintiffs' new allegation regarding licensing is a canard given that (1) Plaintiffs allege no agreement between the Defendants would have prohibited licensing and (2) Plaintiffs themselves have put before the Court evidence that Smiths in fact offered to license the cartridge design to Plaintiffs, but Plaintiffs rejected the offer. *See* Dkt. 11 (Pls.' Application for Order To Show Cause), Ex. C, at 10 (letter on behalf of Smiths to Sandoz noting that Smiths "would be willing to entertain an offer from Sandoz regarding licensing of the cartridge design" and Smiths actually offered a license, which Sandoz rejected).

that actually supply the good or service.” *See, e.g., Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 184 (3d Cir. 1997).

In a bid to show it is no “mere sales agent,” RareGen reaches beyond the Complaint to its purported “partnership agreement” with Sandoz. Opp. at 21 & n.4. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The plaintiff in *Eisai Inc. v.*

Sanofi-Aventis U.S., LLC held an exclusive contract with the drug manufacturer to distribute and sell the drug, 2010 WL 3172187, at *7–8 (D.N.J. Aug. 10, 2010); the plaintiff in *Graco Inc. v. PMC Global, Inc.* exclusively distributed and sold competing products in the same market as the defendant, 2012 WL 762448, at *7 (D.N.J. Mar. 6, 2012). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Under *Barton & Pittinos*, RareGen lacks antitrust standing.

Similarly, RareGen’s rights as an investor with a claim to a portion of Sandoz’s sale proceeds does not confer standing. *See Spinner Consulting LLC v. Bankr. Mgmt. Sols., Inc.*, 2019 WL 2453816, at *10 (D.N.J. June 12, 2019)

(“Merely derivative injuries sustained by employees, officers, stockholders, and creditors of an injured company do not constitute ‘antitrust injury’ sufficient to confer antitrust standing.”); *Vinci v. Waste Mgmt., Inc.*, 80 F.3d 1372, 1375 (9th Cir. 1996) (shareholders, including sole investors, do not have standing to sue for antitrust violations because it creates the possibility of double recovery).

Because RareGen cannot recover for “foreclosure” from the distribution of a drug for which it is not a distributor, Plaintiffs lack antitrust standing. *Assoc. Gen. Contractors of Cal. v. Cal. State Council of Carpenters*, 459 U.S. 519, 545 (1983).

V. Plaintiffs Fail To Plead Cognizable North Carolina Unfair Trade Practices and New Jersey Tortious Interference Claims.

Plaintiffs do not dispute that their state antitrust claims are entirely duplicative of their federal claims and should be dismissed on that account. And their efforts to defend their other two state law claims fall far short.

A. Plaintiffs Do Not Plead Sufficient Facts To Support Their North Carolina Unfair Trade Practices Claim.

Plaintiffs make the uncontroversial point that there are ways to violate North Carolina’s unfair trade practices act other than by violating federal antitrust laws. *Opp.* at 22–23. But Plaintiffs do not plead consumer fraud, deception, or any other non-antitrust basis for their claim. For purposes of N.C.G.S. § 75-1.1, North Carolina courts have imported the definition of “anticompetitive” from federal antitrust cases. *See Exclaim Mktg., LLC v. DirecTV, LLC*, 134 F. Supp. 3d 1011,

1022 (E.D.N.C. 2015) (citing *Dickson v. Microsoft Corp.*, 309 F.3d 193, 206 (4th Cir. 2002) (Sherman Act §§ 1 & 2 case)), *aff'd per curiam*, 674 F. App'x 250 (4th Cir. 2016).⁶ Because Plaintiffs have not alleged a proper antitrust claim, their Section 75-1.1 claim based on the same conduct must fail as well. *Sykes v. Health Network Sols., Inc.*, 2019 WL 2479965, at *4 (N.C. June 14, 2019) (affirming dismissal of Section 75-1.1 claims “to the extent that these allegations overlap” with antitrust allegations, on which reviewing court was equally divided).

B. Plaintiffs Do Not Plead Sufficient Facts To Support Their New Jersey Tortious Interference Claim.

Invoking New Jersey law, Plaintiffs claim they need not plead an antitrust claim to satisfy the “wrongful conduct” requirement for tortious interference, but need only allege a violation of “the rules of the game,” Opp. at 24 (quoting *Platinum Mgmt., Inc. v. Dahms*, 666 A.2d 1028, 1044 (N.J. Super. Ct. Law Div. 1995))—and then use this catchphrase without explaining it. Its meaning is settled and precise: “The line clearly is drawn at conduct that is fraudulent, dishonest, or illegal and thereby interferes with a competitor’s economic advantage.” *Amateur Baseball Ass’n, Inc. v. N.J. Amateur Baseball League, LLC*, 2017 WL 490534, at

⁶ Courts “may” look to FTC Act cases for guidance when interpreting Section 75-1.1, *Ken-Mar Finance v. Harvey*, 368 S.E.2d 646, 649 (N.C. Ct. App. 1988), but have trended away from doing so, as recent opinions do not cite FTC Act authorities. See, e.g., *White v. Thompson*, 691 S.E.2d 676, 679–80 (N.C. 2010); *Gray v. N.C. Ins. Underwriting Ass’n*, 529 S.E.2d 676, 681–82 (N.C. 2000).

*2 (N.J. Super Ct. App. Div. Feb. 7, 2017) (per curiam) (quoting *Lamorte Burns & Co. v. Walters*, 770 A.2d 1158, 1171 (N.J. 2001)).

The cases cited by Plaintiffs, Opp. at 24, all involve precisely what Plaintiffs have failed to allege here: fraudulent acts or dishonest dealing. *See Platinum Mgmt.*, 666 A.2d at 1044 (using confidential information from competitor's former employees to steal customers); *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1169 (3d Cir. 1993) (knowingly spreading false rumors about competitor); *Lamorte*, 770 A.2d at 1164 (removing confidential client information to begin rival business). Here, Plaintiffs' *only* effort to meet the "wrongfulness" requirement of their claim is to assert an antitrust violation. Having failed to plead such a violation, Plaintiffs have doomed their tortious interference claim too.

CONCLUSION

In anticipation of the dismissal of their Complaint, Plaintiffs propose to plead new facts regarding the nature of Defendants' restrictions, but do not—because they cannot—say they will plead facts showing the lack of any alternative means of distribution. That deficiency is incurable, as evidenced by Plaintiffs' admission that UTC has developed other subcutaneous pumps during the same time that Sandoz was preparing its launch. Because amendment would be futile, Defendants' Motion To Dismiss should be granted and Plaintiffs' Complaint should be dismissed with prejudice.

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